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EXAMINER

MENON, KRISHNAN S

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 06/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,322

Applicant(s)

BORMANN ET AL.

Examiner

Krishnan S Menon

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7, 9-14 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1,2,4-7, 9-14 and 17-25 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1,2,4-7, 9-14 and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pall et al (US 5,587,070).

Instant Claim 1: Pall (070) teaches a housing with inlet and outlet having a filter disposed inside (114-fig 4, 12-fig 1, fig 5, col 18 line 54-col 19 line 2, col 27 lines 16-25, claim 1); filter comprising porous fibrous leukocyte depletion medium having CWST >70 dynes/cm (col 13 lines 10-28, col 14 lines 36-40, claims 13 and 14), a second filter of 5 micron or less (col 21 lines

Art Unit: 1723

30-43) and which allows plasma to go through but prevents RBCs and leucocytes (col 6 lines 35-43, col 7 lines 15-20, col 11 lines 12-17, claim 1); and as in instant claim 1.

Pall (070), while teaching combination of filter media that prevent red cells and leukocytes from passing through (col 11 lines 11-17; col 10 lines 21-39; col 30 lines 16-35), is not clear whether the first fibrous leukocyte depletion filter and the second membrane filter are integral in one filter housing. However, it would be obvious to one of ordinary skill in the art at the time of invention to put the first filter and the membrane in the same housing in series to obtain the desired separation of biological fluids while reducing the volume hold-up of the biological fluids (col 28 lines 45-52 – implied concern of hold-up volume), and having compactness, ease of fabrication, and less conduit length.

Claims 4-7,9,17,18 and 24, all depending from 1, and have additional limitations, which are taught by Pall as follows: filter element comprises melt-blown fibers as in instant claim 4 (col 18 lines 17-30); first filter at least two layers (col 33 lines 18-21) as in instant claim 5, CWST >90 dynes/cm as in instant claim 6(see table, and claim 14); first and second containers with filter interposed in between as in instant claim 9(see figures); second filter is a membrane of pore size 0.3- 3 microns (col 21 lines 30-43) as in instant claim 17 and 18; can be arranged to allow platelets to pass as in instant claim 24 (col 6 lines 35-43).

Independent Claim 2 has an added limitation to that recited in claim 1, fibrous red cell barrier (col 11 lines 11-17); claim 19, dependent on claim 2, has the added limitation: second filter is a membrane of pore size 0.3- 3 microns (see col 21 lines 30-43); and claim 25, dependent on claim 2, has the added limitation: the filter being arranged to substantially prevent passage of platelets (see col 18 lines 34-42), all taught by Pall.

Independent Claim 20 has an added limitation to what is recited in claim 2, that is, the filter includes no more than one membrane, which is also taught by Pall (col 11 lines 11-17).

Method claims 10 and 11(both independent): Pall teaches a method of processing a biological fluid comprising passing a red blood cell and leukocyte containing plasma rich biological fluid into a filter device comprising a leukocyte depletion medium and a membrane, and collecting a filtered plasma-rich fluid substantially free of leukocytes and red cells as in instant claims 10 (abstract and fig 1). Claim 11 has the added limitation that the biological fluid to be processed is leukocyte containing plasma-rich biological fluid.

Pall (070), while teaching combination of filter media that prevent red cells and leukocytes from passing through (col 11 lines 11-17; col 10 lines 21-39; col 30 lines 16-35), is not clear whether the first fibrous leukocyte depletion filter and the second membrane filter are integral in one filter housing for the process of instant claim 10 and 11. However, it would be obvious to one of ordinary skill in the art at the time of invention to put the first filter and the membrane in the same housing in series to obtain the desired separation of biological fluids while reducing the volume hold-up of the biological fluids (col 28 lines 45-52 – implied concern of hold-up volume), and having compactness, ease of fabrication, and less conduit length.

Method Claims 12, independent, and 13 depending from 12 have the added limitations to what is recited in claim 11: processing a biological fluid to provide a supernatant layer comprising a leukocyte containing plasma-rich fluid and sediment layer containing a red blood cell containing fluid (col 1 line 62 – col 2 line 63) as in instant claim 12 and wherein the leukocyte containing plasma rich fluid comprises a leukocyte and platelet depleted biological fluid as in claim 13 (col 2 lines 35-42), all taught by Pall.

Art Unit: 1723

Method claim 14 (independent): Pall teaches a method of processing a biological fluid comprising depleting leukocytes and platelets from blood to provide a red blood cell containing fluid, processing the red blood cell containing fluid to provide a supernatant layer containing plasma and sediment layer containing red blood cells (see col 1 line 62-col 2 line 53), passing the supernatant layer through a filter comprising a housing with inlet and outlet having a filter disposed inside (114-fig 4, 12-fig 1, fig 5, col 18 line 54-col 19 line 2, col 27 lines 16-25, claim 1); filter comprising porous fibrous leukocyte depletion medium having CWST >70 dynes/cm (col 13 lines 10-28, col 14 lines 36-40, claims 13 and 14), a second filter of 5 micron or less (col 21 lines 30-43) and which allows plasma to go through but prevents RBCs and leucocytes (col 6 lines 35-43, col 7 lines 15-20, col 11 lines 12-17, claim 1); and collecting the plasma-rich fluid down-stream of the filter device (fig 1)

Pall (070), while teaching combination of filter media that prevent red cells and leukocytes from passing through (col 11 lines 11-17; col 10 lines 21-39; col 30 lines 16-35), is not clear whether the first fibrous leukocyte depletion filter and the second membrane filter are integral in one filter housing for the process of instant claim 14. However, it would be obvious to one of ordinary skill in the art at the time of invention to put the first filter and the membrane in the same housing in series to obtain the desired separation of biological fluids while reducing the volume hold-up of the biological fluids (col 28 lines 45-52 – implied concern of hold-up volume), and having compactness, ease of fabrication, and less conduit length.

Method claim 21 and 22 and 23 depending from 21: Pall (070) teaches the method of processing a biological fluid through a filter (abstract, fig 1), the filter comprising a housing with inlet and outlet having a filter disposed inside (114-fig 4, 12-fig 1, fig 5, col 18 line 54-col 19

Art Unit: 1723

line 2, col 27 lines 16-25, claim 1); filter comprising porous fibrous leukocyte depletion medium having CWST >70 dynes/cm (col 13 lines 10-28, col 14 lines 36-40, claims 13 and 14), a second filter of 0.3 to 3 microns down-stream of first (col 21 lines 30-43) and which allows plasma to go through but prevents RBCs and leucocytes (col 6 lines 35-43, col 7 lines 15-20, col 11 lines 12-17, claim 1); claim 22 has the added limitation that the filter also depletes platelets (col 21 lines 30-43).

Pall (070), while teaching combination of filter media that prevent red cells and leukocytes from passing through (col 11 lines 11-17; col 10 lines 21-39; col 30 lines 16-35), is not clear whether the first fibrous leukocyte depletion filter and the second membrane filter are integral in one filter housing for the process of claims 21-23. However, it would be obvious to one of ordinary skill in the art at the time of invention to put the first filter and the membrane in the same housing in series to obtain the desired separation of biological fluids while reducing the volume hold-up of the biological fluids (col 28 lines 45-52 – implied concern of hold-up volume), and having compactness, ease of fabrication, and less conduit length. Pall also does not teach the volume of fluid to be 500-1000 ml as in the claim 23. However, Pall teaches a filter that could filter 450 ml (Pall '070: col 6 lines 3-9) and it would be obvious to one of ordinary skill in the art at the time of invention that this filter could filter a larger volume with a longer duration of filtering.

Response to Arguments

Re argument that there is no teaching or suggestion in Pall '070 to arrange the media disclosed therein in the precise manner which yields the claimed invention: Col 11 lines 11-15

Art Unit: 1723

teaches that the filter could be a combination of leukocyte depletion medium and red cell barrier medium. Col 12 lines 13-18 teach a separation membrane 14, a membrane with porosity less than 5 microns (col 21 lines 30-43). Col 12 lines 30-35 states that one skilled in the art could configure the assemblies in different combinations. Col 10 lines 21-39 teach use of separation medium that transmits plasma but filters other components from blood. Col 30 lines 16-35 teach assemblies comprising one or more porous media. It would be obvious to one of ordinary skill that if one wants to separate the blood into individual components, one would require separate filters for each component. However, if one is interested in collecting only plasma from the blood or the plasma containing fluid, one could combine the filters in one housing in the line of what is taught in col 10 lines 21-39.

Re argument that the office action has not shown based upon Pall '070 that one would be led to combine the filters, or that reduced volume hold-up would result: Office action has shown that Pall '070 leads one of ordinary skill in the art to combine the filters to filter all other components to obtain plasma from blood, as above. It would be obvious to one of ordinary skill that by reducing the number of housings, one would reduce the volume hold-up (hold-up volume is implied as a concern in col 28 lines 45-52). Examiner believes that the case law (*In re Gorman*, 18 USPQ2d 1885) quoted by the applicant has no bearing on this case. The case law is about combining a large number of references in order to support a rejection of obviousness. The present case is about a single reference and whether there is any explicit or implied suggestion to combine the filters into one housing. The examiner believes that there is sufficient implied suggestion as pointed out in the paragraph above.

Argument re claim 23 that the office action has not explained why one of ordinary skill in the art would be led from the teaching of Pall '070 to the instant claim: see *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955): change of size or shape is not sufficient to patentably distinguish over prior art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 703-305-5999. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 703-308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.


Application/Control Number: 09/806,322

Page 9

Art Unit: 1723

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Krishnan Menon
Patent Examiner
June 9, 2003


JOSEPH DRODGE
PRIMARY EXAMINER